Exhibit A

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**
THIS DOCUMENT RELATES TO ETHICON WAVE 3 MOTIONS	

PLAINTIFFS' OPPOSITION TO DEFENDANTS' MOTION AND MEMORANDUM IN SUPPORT OF ITS MOTION TO EXCLUDE CERTAIN GENERAL OPINIONS OF JERRY BLAIVAS, M.D.

Now come Plaintiffs in opposition to Defendants' Ethicon, Inc., Ethicon LLC, and Johnson & Johnson (collectively "Ethicon") Motion and Memorandum in Support of Motion to Exclude Certain General Opinions of Jerry Blaivas, M.D. ("Dr. Blaivas") ("Ethicon Brief").[1] Plaintiffs show the following:

I. INTRODUCTION

Ethicon seeks to exclude a number of Dr. Blaivas's opinions regarding products manufactured and marketed by Ethicon. These devices include: the TVT, TVT-O, TVT Secur, TVT Exact and TVT Abbrevo, all used to treat stress urinary incontinence, ("SUI") (devices collectively referred to as "TVT devices"), and the Prolift device ("Prolift") used to treat pelvic

[1] Citations to the Ethicon Brief will be in the form (Eth. Br., ___.)

organ prolapse ("POP").[2,3] Ethicon seeks to exclude the following general opinions proffered by Dr. Blaivas: 1) that the TVT devices are not safe to treat SUI; (Eth. Br., 2-8) 2) that traditional surgical approaches are safer than the TVT devices or Prolift; (Eth. Br., 8-12) 3) that synthetic mesh devices manufactured by others are safer alternatives to Ethicon's products; (Eth. Br., 12-17) 4) that Ethicon failed to provide adequate warnings in the various instructions for use ("IFU") accompanying its devices; (Eth. Br., 17) and 5) that mesh is incompatible with the human body particularly insofar as it degrades, shrinks, and deforms. (Eth. Br., 17.)

Ethicon relies almost entirely on deposition testimony that is dated and no longer provides the full support for Dr. Blaivas's opinions. In particular, Ethicon blithely ignores Dr. Blaivas's deposition from August 29, 2016[4] which he proffered regarding both the TVT-Exact but also the other TVT devices at issue here:

> Q. And do many of the opinions that are contained in the TVT-Exact report overlap with the opinions that you have also given in the TVT-Retropubic, TVT-O and TVT-S and TVT-Abbrevo reports?
>
> A. They do.

(Ex. A, 7:9-14.)

Ethicon cannot reasonably challenge that Dr. Blaivas's opinions regarding TVT-Exact can also apply to other Ethicon mesh products since it adopts the same approach, relying to a significant degree on Dr. Blaivas's TVT Report of August 24, 2015. (Eth. Br., 1, n.1)(Ethicon

[2] Dr. Blaivas's reports are designated as exhibits and attached hereto only insofar as they are referenced herein.
[3] Dr. Blaivas has not submitted an expert report regarding the Prolene Soft device and proffers no specific opinions regarding it. However, he is qualified to proffer opinions that softer polypropylene mesh is generally preferable for use in transvaginal devices than the mesh comprising the TVT and Prolift devices at issue here.
[4] Relevant excerpts of the August 29, 2016 deposition are attached hereto as Exhibit A. Future citations to it are in the form (Ex. A, ___:___-___:___.)

stating that "most of Dr. Blaivas's opinions about the TVT devices are the same," and generally limiting its cites to Dr. Blaivas's TVT Report as a result.).[5]

II. PROCEDURAL HISTORY

Ethicon originally noticed Dr. Blaivas's deposition for August 29, 2016 but canceled it on two hours' notice with little warning either to Dr. Blaivas or to Plaintiffs' counsel.[6] Ethicon's stated reason was that Plaintiffs have neither adopted Dr. Blaivas's TVT-Exact Report in Wave 3 nor issued a new report on the device in Wave 3. Its argument ignores a fact about which both parties share total agreement: the testimony Dr. Blaivas proffered about Ethicon's products was not confined to any one device but was generally applicable to his opinions about TVT devices in whole. (*See* Ex. A, 7:9-14)(Dr. Blaivas testifying that his opinions about the TVT-Exact overlap with his opinions about TVT devices in general)(*see also* Eth. Br., 1, n.1.) Ethicon cannot have it both ways. It clearly relies on Dr. Blaivas's testimony about the TVT in seeking to exclude his opinions not only about that device but also other Ethicon products. As such, it cannot credibly argue that Dr. Blaivas's testimony from August 29, 2016 is somehow irrelevant to the Wave 3 cases.

Ethicon should also be precluded from arguing that it is unaware of testimony Dr. Blaivas offered August 29, 2016.[7] In fact, Ethicon was on notice that Plaintiffs planned to conduct the noticed deposition. (*See* Ex. C.) It certainly could have requested a deposition transcript but did not. That Ethicon has chosen not to recognize the August 29, 2016 deposition is of no

[5] Ethicon also cites extensively in the Ethicon Brief to Dr. Blaivas's deposition testimony of September 17, 2015, during which he proffered testimony about the TVT retropubic device. Relevant excerpts of the September 17, 2015 deposition transcript are attached hereto as Exhibit B. Future citations to it will in the form (Ex. B, ___:___; ___:___.).

[6] (*See* email dated August 29, 2016 at 9:25 a.m. from Ethicon's attorney Tracy J. Van Steenburgh ("Ms. Van Steenburgh") to Plaintiffs' attorney Fidelma Fitzpatrick ("Ms. Fitzpatrick") indicating that Ethicon planned to cancel the deposition they noticed for later that day.) (The email chain including both Ethicon's intention to cancel the deposition and Ms. Fitzpatrick's plan to go forward as scheduled with Dr. Blaivas's testimony is attached here as Exhibit C. Future reference to it will be in the form (Ex. C, ___.).)

[7] For the record, Ethicon does not raise the argument in the Ethicon Brief and should not be able to raise it in reply.

consequence. Dr. Blaivas's testimony is properly before the Court and serves to provide important support for his opinions about the TVT devices.

III. DR. BLAIVAS'S QUALIFICATIONS

Ethicon, without justification, seeks to exclude several of Dr. Blaivas's opinions on the basis of his qualifications. Dr. Blaivas is a recognized leader and a pioneer in the field of reconstructive surgery for women, especially sling surgeries for the treatment of incontinence.[8] Following medical school, he completed both a general surgical residency and one in urology. (*Id*.) He has devoted his career to an active surgical practice, focusing in particular on treating women with severe complications from mesh devices, (*id.*, 2-3) while also serving as a medical school professor at several prestigious institutions. (*Id*, 1.) He is board certified in urology. (*Id*.) Dr. Blaivas publishes regularly in leading peer-reviewed academic journals and other publications. (*Id*., 1, 3.)

IV. LEGAL STANDARD

The task of evaluating the reliability of expert testimony is uniquely entrusted to the district court. *Daubert v. Merrell Dow Pharmaceuticals, Inc*. 509 U.S. 579, 589 (1993). District courts enjoy "considerable leeway" in determining the admissibility of expert testimony. *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999). A trial judge's decision to admit expert testimony is reviewed only for an abuse of discretion, and reviewing courts will not find an abuse unless a ruling is "arbitrary and irrational." *United States v. Cloud*, 680 F.3d 396, 401 (4th Cir. 2012); *Cavallo v. Star Ent.*, 100 F.3d 1150, 1153 (4th Cir. 1996); *United States v. Dorsey*, 45 F.3d 809, 812 (4th Cir. 1995).

[8] (*See* Rule 26 Expert Report of [Dr. Blaivas] dated February 1, 2016 attached hereto as Exhibit D at 1. Future citations to Exhibit D will be in the form (Ex. D, ___.).)

Under Federal Rule of Evidence ("Rule") 702, if scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education may testify thereto in the form of an opinion or otherwise, provided the testimony (1) is "based upon sufficient facts or data" and (2) is "the product of reliable principles and methods," (3) which have been reliably applied "to the facts of the case." *In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 601 (S.D.W. Va. 2013). A two-part test governs the admissibility of expert testimony. The evidence is admitted if it "rests on a reliable foundation and is relevant." *Daubert v. Merrell Dow Pharm.*, 509 U.S. 579, 597, 113 S.Ct. 2786, 125 L.Ed.2d 469 (1993).

The testimony Dr. Blaivas seeks to proffer is in full compliance with the standards set forth in Rule 702, *Daubert*, and its progeny. *See* Rule 702; *see also Daubert*, 509 U.S. at 597 (to be admitted, evidence must "rest [ ] on a reliable foundation and [be] relevant"); *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 262 (4th Cir. 1999) ("[T]he obligation of a district court to determine whether expert testimony is reliable and relevant applies to all expert testimony [i.e. scientific and non-scientific]."); *Davis v. U.S.*, C. A. No. 5:10-CV-00384, 2011 WL 7053628 at *2 (S.D.W. Va. September 16, 2011) (The court applied Rule 702/*Daubert* principles in deciding that the expert qualified as a Life Cycle Planner and that her methodologies were sufficiently reliable under law.). To the extent applicable, Dr. Blaivas's testimony is also within the bounds of Rule 104(a). *See* Rule 104(a). In addition, Plaintiffs aver that the law requires that Rule 702 be applied flexibly, *see Daubert*, 509 U.S. at 594, so as to uphold the general framework of the Rules which favors the admissibility of evidence over non-admissibility. *Id*. at 588. In short, "the rejection of expert testimony is the exception rather than the rule." *U.S. v. Stanley*, No. 12-4572, 2013 WL 3770713 at *1 (4th Cir. July 19, 2013) (internal quotations omitted in the cited

quotation.). Plaintiffs respectfully move that the expert testimony proffered by Dr. Blaivas should be admitted in full and that Ethicon's motion should be denied.

V. LEGAL ARGUMENT

A. DR. BLAIVAS'S OPINIONS THAT TVT DEVICES ARE UNSAFE ARE RELIABLE, ARE NOT CHERRY-PICKED, AND ARE GROUNDED FULLY IN THE RIGOR HE BRINGS TO HIS PRACTICE

Ethicon challenges a wide range of Dr. Blaivas's safety and efficacy opinions. (Eth. Br., 2-8.) Ethicon's arguments – particularly that the opinions are identical to ones the Court has excluded previously (Eth. Br., 2-3) – are without merit and Dr. Blaivas's opinions should be admitted for the reasons set forth herein.

1. Dr. Blaivas's Opinions About Complication Rates Are Reliable.

Ethicon argues that Dr. Blaivas's opinion is that TVT Devices have a minimum complication rate of 12.5% and that he ostensibly grounds his opinions in one article he co-wrote with Dr. Iakovlev, "Safety Considerations for Synthetic Sling Surgery." (Eth. Br., 3.) Such ignores both the true scope of Dr. Blaivas's opinions regarding complication rates as well as the breadth of the extensive scholarship he grounds them in.

In fact, Dr. Blaivas's opinion is that the overall complication rate after implant surgery is ≥ 15% with a risk that the numbers are actually somewhat underreported since patients who have complications often will not return to their original surgeons with their problems going unnoted by implanters.[9] His opinions are amply supported by his own scholarship, along with a number of other academics. (*See Id.*, 10-11 and notes thereto.) (*See also* Timbrook Brown E, et. al., Evaluation and Management of Mid-Urethral Sling Complications, Curr. Bladder Dysfunct. Rep., 2016 Apr 18:1-9 ("Brown Article").)[10]

[9] (*See* Ex. D at 10-11 (subpoints 30-31); *see also supra.* 2.).
[10] The Brown Article is attached hereto as Exhibit E. Future citations to Exhibit E will be in the form (Ex. E, ___.).

Ethicon takes particular issue with Dr. Blaivas's 2015 review article that he uses to support his complication rate opinions, arguing that it does not explain the methodology used for deriving the 12.5% complication rate and because it ostensibly evidences cherry-picking of data. (Eth. Br., 3-4.) Both are untrue. The review article included all available data between 2007-2014 and also included pathology from years before that. (Ex. A, 21:12-16.) The search criteria utilized to find data was extensive (*see id*., 22:10-24:1) and was chosen precisely so Dr. Blaivas and his collaborators would not miss anything crucial:

> Q. Why did you have so many search terms?
>
> A. 'Cause we didn't want to miss any articles, and what we did is we would look up - - we started with less search terms and we read articles, we would see synonyms or new words and then we would add that to the search term.

(*Id*., 24:6-13) (*see also Id*., 24:14-25:3.) (evidencing that Dr. Blaivas's team considered in excess of thirty relevant search terms).

Far from cherry-picking, from the earliest stage of drafting the review article, Dr. Blaivas employed a method that enabled him to access as wide a range of available scholarship as possible. Indeed, the one exclusion criterion he used made complete sense since it prevented duplicate patients from being counted repeatedly, thereby preventing the skewing of data. (*Id*., 24:21-26:1.)

This methodology resulted in a review article that considered both safety and efficacy[11] for mesh devices (*id*., 26:19-23) and was grounded in solid data. For example, regarding complications:

[11] Many of the issues that Ethicon purports to have with the 2015 review article is because it improperly conflates the complications and efficacy data which Dr. Blaivas and his collaborators address separately in the article. (*See* Eth Br., 3-4) (*See also* Ex. A, 73:4-76:28) (Dr. Blaivas testifying that his article distinguishes between complication rates and efficacy rates and also excludes data on POP devices, all contrary to Ethicon's arguments which conflate Dr. Blaivas's data, thereby incorrectly challenging it.) (*See also* 29:10-31:5) (Dr. Blaivas testifying that some articles were considered for efficacy and some for safety). (*See also* 58:13-59:13) (Dr. Blaivas's methodology for reaching incidence of complications and incidence of efficacy).

> Q. Tell me why you thought [his research method] was an appropriate way to achieve that result.
>
> A. Because I wanted to be sure on the one hand that we captured every complication, but on the other hand we didn't count anybody twice 'cause we were looking to get as precise a number for both - - for complications as we could. We didn't want to overestimate; we didn't want to underestimate.

(*Id*., 26:8-18.)

And regarding efficacy:

> Q. Was there different criteria that you looked at for articles relating to efficacy?
>
> A. Yes. For articles for efficacy we only included those articles that measured efficacy, that had appropriate follow-up, and we did have criteria for that.

(*Id*., 27:3-10) (*see also Id*., 27:11-16) (Dr. Blaivas testifying that there were more exclusion criteria for the efficacy data than for the safety.).

This care in scholarship resulted in avoiding cherry-picking entirely:

> Q. Did you in any way cherry pick or look only for reports or articles that dealt with high rates of complications?
>
> A. No.

(*Id*., 28:3-29:9.) (*See also Id*., 28:3-29:9)(Dr. Blaivas testifying extensively about the methodology of choosing articles for the 2015 Review); *id*., 38:1-23) (all available articles included unless they relied on flawed methodology.).

Ethicon also challenges Table 1 of Dr. Blaivas's review paper. (Eth. Br., 3-4.) In fact, Dr. Blaivas testified that Table 1 relates to ***efficacy*** rates and not to ***complication*** (safety) rates as Ethicon contends. (Ex. A, 29:10-21.) Therefore, Ethicon's challenges largely fail on their faces. In addition, the data that Ethicon contends is "missing" from Table 1 (Eth. Br., 4) actually was considered by Dr. Blaivas and his colleagues as relating to their proper topic - - safety:

> Q. So you can't say that simply because something isn't on the Table 1 that you didn't rely on it, use it, conclude anything about it or consider it as part of your safety considerations and complication considerations; is that right?
>
> A. To the contrary; we would have used it.

(*Id*., 30:21-31:5.)

Ethicon also challenges Dr. Blaivas's review article because it considered mesh products that were not manufactured and marketed by Ethicon. (Eth. Br., 4.) Such ignores that Dr. Blaivas is allowed to rely on his clinical experience in proffering expert testimony. *See* Rule 702. That is precisely what he did in proffering his opinions regarding the safety and efficacy of the TVT Devices:

> Q. And do you rely on your clinical experience for your opinions that the TVT-Exact and the Ethicon midurethral slings can cause these types of complications in women?
>
> A. They do.

(Ex. A, 63:13-18.)

His clinical experience includes both Ethicon and non-Ethicon products and his entire experience informs his opinions related to TVT devices. (*See Id*., 64:19-68:9)(Dr. Blaivas testifying at length about the methodology he and his colleagues used to determine the complication rate generally for women implanted with mid-urethral slings.); (*See also*, Ex. E.)

And finally, Ethicon takes false comfort in this Court's previous ruling in *Huskey v. Ethicon*, 29 F.Supp.3d 691, 721 (S.D.W. Va. 2014.). (Eth. Br., 3.) As this Court has observed, the parties must be careful not to cite the Court's previous opinions when facts have changed. *See In re Ethicon Pelvic Repair Systems Product Liab. Litig.*, MDL No. 2327, 2016 WL 4500767 at *1 (S.D.W. Va. August 26, 2016). Such a change has clearly happened here where Dr. Blaivas

did not have access to the data undergirding his 2015 review and his current opinions when he testified in Ms. Huskey's case:

> Q. Can you tell me why you can be certain about complication rates in August of 2015 when you couldn't be certain about complication rates in the summer of 2014?
>
> A. Because we did such an exhaustive search of the literature and this is our best estimate of the minimum complication rate. I emphasize that.

(Ex. A, 70:17-24.)

Dr. Blaivas's opinions regarding the safety and efficacy for TVT Devices are adequately supported by reliable methodology. They must be admitted. *See Daubert*, 509 U.S. at 597.

2. Dr. Blaivas's Opinions Regarding Rates Of Dyspareunia And Sexual Dysfunction Are Reliable And Should Be Admitted.

Ethicon would have this Court exclude Dr. Blaivas's opinions on the rate of dyspareunia and sexual dysfunction from TVT devices because they are ostensibly in disagreement with AUA guidelines. Ethicon's argument evidences, among other things, its misinterpretation of Dr. Blaivas's deposition from September 2015. (Eth. Br., 4-5.) Dr. Blaivas's opinions are reliable and should be admitted. *See Daubert*, 509 U.S. at 597.

First, as Dr. Blaivas testified, he was a member of an AUA committee that developed the guidelines in question. (Ex. A, 78:4-5.) The opinions expressed, including those related to the safety and efficacy of midurethral slings, were those of the committee ***as a whole*** and did not represent Dr. Blaivas's personal medical opinion. (*Id.*, 78:5-24.) Dr. Blaivas's own opinion is not as expansive as the AUA's position that mesh products are suitable surgical alternatives. Rather, he finds them appropriate treatment options only for a very small number of patients who are warned of and accept the risks. (*Id.*, 79:5-80:11)(identifying certain non-sexually active, older, and/or obese patients as potential candidates if warned properly.). In short, notwithstanding

anything said in the AUA guidelines, Dr. Blaivas's opinion is that midurethral mesh devices are not proper first line treatments for all women. (*Id*., 81:7-12.)

Ethicon also selectively cites to Dr. Blaivas's deposition of September 17, 2015 regarding the AUA data. In fact, Dr. Blaivas testified there that he was compelled to rely on faulty data with which he disagreed. (Ex. B, 161:4-162:14)(Dr. Blaivas testifying, among other things, that the data was weak but the "dictates of the organizing body" compelled the committee to use it anyway.). Dr. Blaivas's academic experience allowed him to know the data was flawed:

> Every single study in the literature I ever reviewed that looked at any - - either sexual - - either dyspareunia or pain has an incidence higher than 1 percent. So I don't know how this happened - - I don't know how this occurred.

(*Id*., 162:7-14.)

Dr. Blaivas's opinions that mesh is not a suitable surgical option for all women is well-supported by the existing clinical literature. (*Id*.) It is reliable and should be admitted. *See* Rule 702(b)(d) (a qualified expert may offer expert testimony that is based on "sufficient facts or data" reliably applied to the case.). The fact that it conflicts with the AUA guidelines (which Dr. Blaivas disavows in part) goes to the weight of his opinions and not their admissibility. *See Hall v. Boston Scientific Corp*., C.A. No. 2:12-cv-08186, 2015 WL 868907, at *23 (S.D. W. Va. Feb. 27, 2015) (admitting medical expert's general opinions and holding that it is not the Court's place at the *Daubert* stage to decide the "rightness" of an expert's conclusions; it should focus on whether the expert's methodology was sound: "Whether Dr. Ostorgard correctly interpreted this research has no bearing on the admissibility of his opinions.").

In addition, the AUA guidelines also support that various alterative procedures may be useful treatment options, as opposed to mesh slings. (Ex A, 83:84-2.) The AUA does not conclude that mesh slings are safer alternatives to non-mesh surgeries or that physicians should only

consider mesh options for women suffering SUI (*Id*., 84:6-17.) To the extent that Dr. Blaivas relied on the AUA guidelines for this opinion, they are reliable and should be admitted. Likewise, to the extent that Ethicon argues that Dr. Blaivas's opinions regarding the safety of alternative procedures, including autologous slings, are not reliable based on issues it finds with Dr. Blaivas's complication rates data, his opinion should be admitted since Ethicon's arguments erroneously conflate Dr. Blaivas's efficacy and safety data. (*See*, *supr*a. 6-10)

3. Dr. Blaivas's Opinions Regarding Erosion, Extrusion, Exposure, And About Alternative Surgical Procedures Are Grounded In Extensive Scholarship, Are Reliable, And Should Be Admitted.

Ethicon recycles an old argument, arguing that Dr. Blaivas's opinions on rates of extrusion, erosion, and exposure are grounded solely in his personal experience and do not account for contrary scientific literature. (Eth. Br., 5-6, citing *Wineberger*, 2015 WL 1887222 at *10 and *Cisson v. C. R. Bard, Inc.*, 948 F.Supp.2d 589, 606 (S.D.W. Va. 2013)). In fact, Dr. Blaivas's opinions are supported in the scientific literature. (*See* Ex. E, 1) (*see also* Nolfi Al, et. al., Host Response to Synthetic Mesh in Women with Mesh Complications, Am J Obstet Gynecol 2016; 215:206.e1-8 ("Nolfi Article")).[12]

And in closely-related arguments, Ethicon poses a lengthy challenge to Dr. Blaivas's opinions that alternative surgical procedures are safer than mesh slings. (Eth. Br., 8-12.) Ethicon's arguments should be rejected and Dr. Blaivas's opinions admitted in full. As this Court found in *In re Ethicon*, an expert may reliably ground his opinions about alternative procedures in his own experience, particularly where "'the witness [can] explain how the experience leads to the conclusion reached, why that experience is a sufficient basis for the opinion, and how that experience is reliably applied to the facts.'" 2016 WL 4500767 at *3 (quoting Rule 702 advisory

[12] The Nolfi Article is attached hereto as Exhibit F. Future references to Exhibit F will be in the form (Ex. F, ___.).

committee's note to 2000 amendment.)(the Court ultimately reserving its opinion in the case before it since it lacked sufficient information regarding the connection between Dr. Blaivas's opinion and his experience.). Contrary to Ethicon's argument and, unlike the situation the Court faced previously regarding Dr. Blaivas's alternative procedures, he provides ample support to connect his experience with his opinions:

> Q. [D]o you believe that the non-mesh surgical options, and particularly the autologous fascial sling, are safer procedures for women who have [SUI] generally?
>
> A. I do.
>
> Q. Tell me what the basis for that opinion is.
>
> A. Well, because the autologous slings simply don't have any of the devastating kind of complications that we talk about. For practical purposes, no refractory pain and there's, for practical purposes, no erosion, and for practical purposes, there's no fistulas. I mean, the really serious complications, the autologous sling does not have.
>
> Q. Now, Ethicon has asserted that you based your opinions on the benefits of autologous slings solely on your own unreliable personal experiences. Is that correct?
>
> A. ***I wonder why they call my published peer-reviewed articles unreliable, but no, that's not correct.***
>
> Q. What else do you base it on?
>
> A. The peer review literature and speaking with my associates.
>
> Q. Okay.
>
> A. My colleagues.

(Ex. A, 85:1-86:6.) (emphasis added.)

Indeed, Dr. Blaivas grounded his opinions in his study of every available article on the complication rates associated with autologous fascial slings. (*Id.*, 86:9-87:14.14.) (*See* Ex. E) (*See also* Medina CA, et. al., Evaluation and Surgery for Stress Urinary Incontinence: A FIGO Working

Group Report, Neurourol. Urodyn. 2016 Mar 7 ("Medina Article"), Bang, et. al., Autologous Pubovaginal Slings: Back to the Future or a Lost Art? Research and Reports in Urology, 18 Jan 2016, Vol. 216:8, pg. 11-20 ("Bang Article"), Mock, et. al., Contemporary Comparison Between Retropubic Midurethral Sling and Autologous Pubovaginal Sling for Stress Urinary Incontinence after the FDA Advisory Notification, Urology 2015; 85:321-325 ("Mock Article").)[13] His opinions are grounded in experience and reliable literature. They should be admitted. *See* Rule 702.

4. Dr. Blaivas Has Not Engaged In "Selective Choosing" Of His Materials And Adequately Accounts For Contrary Scientific Evidence.

As already set forth herein at length, Dr. Blaivas has not cherry-picked or in any other way engaged in selective-choosing of any of his reliance materials. In fact, time and again, he testified to how he considered the full body of available materials in proffering his opinions. (See Ex. A, 20:10-14; 22:1-26:1; 27:17-29:9; 30:21-31:5; 37:6-38:5; 45:7-46:11.) Ethicon is quite simply factually wrong. Dr. Blaivas grounds his opinions on the scientific materials and experience typically relied on by physicians in his field and his opinions should be admitted in full. *See Kumho Tire v. Carmichael*, 526 U.S. 137, 152 (1999); *see also Hall* 2015 WL 868907 at *23 (admitting medical expert's general opinions and holding that it is not the Court's place to decide the "rightness" of an expert's conclusions but rather, it, should focus on whether the expert's methodology was sound.).

B. DR. BLAIVAS IS QUALIFIED TO TESTIFY ABOUT THE BIOMATERIALS COMPRISING THE TVT DEVICES AND HIS OPINIONS ARE RELIABLE AND SHOULD BE ADMITTED

[13] The Medina Article is attached hereto as Exhibit G. The Bang Article is attached hereto as Exhibit H. The Mock Article is attached hereto as Exhibit I. Future cites to these exhibits will be in the form (Ex. G, ___), (Ex. H, ___), and (Ex. I, ___), respectively.

Ethicon seeks to exclude Dr. Blaivas's opinions regarding the biomaterials aspects of TVT Devices and of the Prolift, including his opinions regarding the weight and pore size of the mesh used, along with his opinions regarding mechanical-cut versus laser-cut mesh. (Eth. Br., 13-15.) Ethicon's arguments lack merit and Dr. Blaivas's opinions should be admitted.

This Court has previously held that urologists and urogynecologists with extensive experience with mesh devices are qualified to proffer opinions on the design aspects of mesh devices, including the polypropylene used to construct them. *See Wise v. C. R. Bard, Inc.*, C. A. No. 2:12-cv-01378, 2015 WL 521202 at *14 (S.D.W. Va. February 7, 2015). Dr. Blaivas possesses the precise experience previously found adequate by the Court and he should be found qualified to proffer his opinions here.

Dr. Blaivas's design opinions are also reliably grounded in his experience with mesh products and also in his study of the available scientific literature. This literature includes very recent articles included in his Supplemental Report which support Dr. Blaivas's opinions regarding pore size. (*See* Ex. F)("[Pointing] to the importance of maintaining meshes in a flat (as opposed to folded) configuration to minimize the amount of material per area and choosing meshes in which spaces between fibers (pores) are wide enough that the host response to two adjacent fibers does not overlap.")(internal quotation omitted.).

Ethicon argues without basis that Dr. Blaivas's opinions about the cut of mesh are inconsistent. (Eth. Br., 15.) In fact, Dr. Blaivas clearly articulates his opinion that laser-cut mesh is stiffer than mechanically-cut. (Ex. D, 15.) Likewise plain is his opinions that Ethicon has not conducted clinical studies to ascertain whether there are consequences to the varying stiffness of the two cuts, (*id*) and has not warned physicians that data regarding mechanical-cut mesh may not

be at all relevant to the stiffer laser-cut product, meaning that different surgical tensioning may be required, depending on the product used. (*Id*., 16.)

C. DR. BLAIVAS IS QUALIFIED TO PROFFER OPINIONS ABOUT THE TVT DEVICES' IMPLANTATION DESIGN AND HIS OPINIONS ARE RELIABLE

Ethicon argues that Dr. Blaivas cannot offer opinions that devices designed for a bottom-to-top surgical approach are more dangerous than those designed for a reverse top-to-bottom approach. Ethicon's arguments are without merit and Dr. Blaivas's opinions should be admitted.

First, Ethicon takes misplaced comfort in the fact that the company also allegedly designs and markets products with top-to-bottom approaches. (Eth. Br., 15.) However, this is irrelevant since Ethicon markets devices with the bottom-to-top approach that Dr. Blaivas finds especially objectionable. Ethicon also argues that Dr. Blaivas selectively chooses his information to support his opinion that a top-to-bottom approach causes less injury in patients, particularly bladder perforations. (Eth. Br., 16.)

In proffering his opinion, Dr. Blaivas, as allowed by law,[14] relies on his extensive surgical experience and his knowledge of the similar experience of his colleagues:

> Q. Do you know whether your opinion that proceeding from the top down as opposed to bottom up would lead to less risk of urethral perforation and other complications has been tested in any randomized control trials?
>
> A. The technique that I'm talking about has not been done for this, so hasn't been tested.
>
> But, it's been done thousands of times by me and other people that do autologous slings.

(Ex. B, 136:4-21.)

[14] *See* Rule 702 ("A witness who is qualified as an expert by knowledge, skill, experience, training or education may testify in the form of an opinion or otherwise if: (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue.")

Ethicon's challenge to Dr. Blaivas's reliance materials regarding his "surgical approach" opinions is likewise groundless. His opinions are well-reasoned that the trocar passage Ethicon instructs is dangerous and are supported in his experience, that of his colleagues, and in the literature. (Ex. A, 39:17-44:19.) To the extent that Ethicon cites to contrary authority, it goes to the weight of Dr. Blaivas's testimony and not to its admissibility. *See Hall*, 2015 WL 868907 at *23)(admitting medical expert's general opinions and holding that it was not the court's place to decide the "rightness" of an expert's conclusions but should focus on whether the expert's methodology was sound.).

D. DR. BLAIVAS'S OPINIONS THAT THE DESIGN OF THE TROCARS AND THE BLIND PASSAGE REQUIRED FOR IMPLANT OF TVT DEVICES CAUSE COMPLICATIONS SHOULD BE ADMITTED

Dr. Blaivas's opinions that Ethicon's design for the trocars used to implant the TVT devices renders them too large should be admitted. With due respect to the Court's earlier opinion excluding Dr. Blaivas's like opinions, *see In re Ethicon*, 2016 WL 4507667 at *4, he amply supports his opinion in his wealth of surgical experience and that of his colleagues who implant autologous slings. (*See* Ex. B, 132:18-133:10)(testifying that by using the much narrower Stamey needle instead of Ethicon's trocars in connection with the top-to-bottom approach, the risk of injuring adjacent organs falls nearly to 0)(*see* Ex. A, 39:20-44:19). Dr. Blaivas also relied on literature from the scientific canon to support his opinions that the trocars used to implant TVT devices were the cause of severe complications especially bladder perforations. (*Id*., 42:15-46:6.) Dr. Blaivas's opinions should be admitted. *See* Rule 702.

E. DR. BLAIVAS'S OPINION THAT THE TVT-ABBREVO AND THE TVT-O ARE SUBJECT TO COMPLICATIONS ARE RELIABLE AND SHOULD BE ADMITTED

Ethicon argues that Dr. Blaivas's opinions concerning the mesh length of the TVT-Abbrevo and his opinions about the TVT-O are unreliable and should be excluded. (Eth. Br., 16-17.) Regarding the TVT-Abbrevo, Dr. Blaivas's opinions about laser-cut mesh are well-supported as set forth previously herein. (*Supra*. 15.) They should be admitted. Dr. Blaivas grounded his opinions about the TVT-O in his testimony that surgery in the obturator space (required for implant of the TVT-O) increases the rate of complications. (*See e.g.*, Ex. B, 76:6-22 [transobturator slings causing serious thigh infections]). He supports his opinion in the literature (*see* Ex. A, 21:8-9 [his search terms for his review of the literature about complications carried terms that would capture transobturator devices]). His opinions should not be excluded.

F. DR. BLAIVAS'S OPINIONS THAT THE WARNINGS ETHICON PROVIDES WITH ITS MESH DEVICES ARE INADEQUATE SHOULD BE ADMITTED

This Court has previously held that surgeons with experience in female pelvic reconstruction, such as Dr. Blaivas possesses, are qualified to testify about the risks of implanting pelvic mesh and whether those risks appeared on a manufacturer's IFU. *See Wise v. C. R. Bard*, 2015 WL 521202 at *14. It is these risks - - specifically-tailored to implanting mesh that Dr. Blaivas testifies about and his opinions should be admitted. This includes his opinions that the IFU does not warn implanting surgeons that mesh is not inert and would not stay the same in the body once implanted. (Ex. B, 36:3-15.) This failure to warn by Ethicon directly leads to severe complications in women who receive the company's products. Dr. Blaivas's opinions are reliable and should be admitted.

G. DR. BLAIVAS'S OPINIONS ABOUT THE BIOMATERIALS USED IN MESH DEVICES AND ABOUT DEGRADATION, SHRINKAGE AND DEFORMATION SHOULD BE ADMITTED

In *In re C. R. Bard, Inc.*, 948 F.Supp.2d 589, 612, the Court held that a practicing urogynecologist was qualified to proffer opinions about the biomaterial aspects and design of mesh

devices, holding that he had "extensive experience with pelvic floor disorders and the use of mesh to treat such disorders." Dr. Blaivas also possesses extensive experience in the design aspects of mesh devices from his years of clinical experience in removing them. (Ex. A, 14:10-16:11.) Therefore, Dr. Blaivas is qualified to proffer the biomaterials opinions that Ethicon would have this Court exclude. (Eth. Br., 17-18.)

Furthermore, Dr. Blaivas's opinions are reliable. They are grounded in both his extensive clinical practice where he has seen deformed mesh that he removed during explant surgeries (Ex. A, 87:15-21) and has also seen degraded mesh:

> Q. And mesh degradation, have you seen mesh falling apart when you take it out of women?
>
> A. I have.
>
> Q. Is your clinical experience in observing each of these phenomenon [i.e. deformation and degradation] a basis for your opinion that each of those things can happen?
>
> A. Yes.

(*Id*., 86:2-10.); *see also In re C. R. Bard*, 948 F.Supp.2d at 612 (admitting the opinions of a urogynecologist regarding the biomaterials of mesh, citing to the physician's experience with pelvic floor disorders and the use of mesh devices for treatment of them.).

Importantly, Dr. Blaivas also grounds his biomaterials opinions in extensive study of the available scientific literature. (*See Id*., 86:15-90:20) (Dr. Blaivas testifying that his opinions are grounded in the research of a colleague but also in studies in the literature that are listed in his reliance materials.). Dr. Blaivas's opinions regarding biomaterials should be admitted.[15] *See* Rule 702.

[15] (*See*, *supra*. n. 3.).

VI. CONCLUSION

For the reasons of the foregoing, Dr. Blaivas's general opinions are reliable and should be admitted in full.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on October 10, 2016, I electronically filed the foregoing document with the Clerk of the court using CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

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